

“tough sell, perhaps because there is an emphasis on treatment but not prevention,” Chaisson told a press conference. “There seems to be a fear of developing resistance and of toxicity, but these are not warranted. Isoniazid has been studied perhaps more than any other treatment in medicine.”

TB prevention, diagnostic and treatment services must become core functions of all HIV services in countries with a high prevalence of TB, De Cock said. People with HIV need to be screened for TB and get prophylaxis and people with TB need to be screened for HIV: “We need one-stop shopping.” — Ann Silversides, Toronto

DOI:10.1503/cmaj.061122

Microbicide update

The US\$62-billion Bill and Melinda Gates Foundation has poured money into microbicide research, because a woman “should never need her partner’s permission to save her own life,” Bill Gates told the opening session of the XVIth International AIDS Conference in August.

Microbicides are applied to the vaginal or rectal surface before sex in order to prevent HIV infection. Microbicide research began in the early 1990s, but it did not receive a great deal of funding or attention until a few years ago after the establishment of the non-profit International Partnership for Microbicides in 2002 brought new energy to the field.

There are now 5 gels, which must be applied immediately before sex, in phase 3 clinical trials. The products in earlier stages of development use direct anti-retroviral effects. For example, a gel form of the drug tenofovir is in phase 2 trials.

A long-term goal is to develop a formulation or device that allows for the slow release of microbicide over a period of days or months. However, researchers are concerned that limited clinical trial capacity in countries with high rates of HIV infection is hampering advances. — Ann Silversides, Toronto

DOI:10.1503/cmaj.061124

Canada falters on promise of AIDS drugs for Africa

Canada will immediately review the federal legislation intended to facilitate the timely production and export of affordable, life-saving drugs to the developing world, pledged federal Health Minister Tony Clement at the XVIth International AIDS Conference in Toronto.

The legislation, introduced more than 2 years ago by the former Liberal government, has come under fire because no drugs have been shipped from Canada.

Apotex, the Canadian generic company that stepped forward and developed a triple-combination HIV/AIDS drug for export, has been frustrated by the lengthy process. But company officials say they are more optimistic now that the World Health Organization has given the drug its stamp of approval.

The WHO prequalification, which was granted just before the AIDS conference began in August, gives developing world countries “a sense of security [that] now they can make a free choice” to seek to import the Apotex drug, explained Bruce Clark, vice-president of regulatory affairs.

Canada received kudos as the first country to pass legislation allowing its generic drug manufacturers to produce copies of patented medicines to be shipped to those who need them.

The vast majority of HIV/AIDS drugs now used in the developing world are manufactured by generic drug companies in countries that, until recently, did not have to comply with international patent rules. India, for example, supplies a significant proportion of HIV/AIDS drugs under the Global Fund. It passed legislation last year to comply with the patent rules, but can still produce copies of AIDS drugs patented in the earlier years of the epidemic.

The Canadian legislation became possible as a result of a provision adopted 3 years ago by the World Trade Organization, whose members agreed that the health needs of people in the developing world should take precedence over international patent agreements.

With the non-governmental organization Médecins Sans Frontières agree-



Canapress

Thousands of people gathered for an AIDS vigil in Toronto on Aug. 17.

ing to act as “broker,” Apotex developed a 3-in-1 drug for which there is no brand name equivalent. The drug combines ziduvodine (AZT), lamivudine (3TC) and nevirapine.

However, the Apotex drug has not yet been exported. The company says it is hung up in negotiations to obtain voluntary licences from the 3 patent-holding pharmaceutical companies involved. Such negotiations must take place, and be unsuccessful, before generic companies become eligible under the law to apply for compulsory licences.

As part of its application for a compulsory licence, Canadian law also requires generic companies to identify the developing country that is the intended recipient of a shipment. To date no country has publicly come forward to request the drug. Apotex’s Clark attributes that reluctance to a country wondering “why should they be required to identify themselves in someone else’s process.” But the WHO pre-qualification should make countries more willing to come forward, he said, and Apotex is preparing its compulsory licence application.

Meanwhile, Anil Soni of the Clinton Foundation said he would be “thrilled” to see Canada issue a compulsory licence to export copies of life-saving drugs. Soni noted that the Apotex price for the new combination drug — the company is charging only its cost — is one-third less than what is now being